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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91206212
Party	Defendant entrotech, inc.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the matter of application Serial Nos.:

85/499,349 for the mark **CHLORADERM** 85/499,345 for the mark **CHLORABSORB** 85/499,337 for the mark **CHLORABOND** 85/499,332 for the mark **CHLORADRAPE**

Filed on December 19, 2011 Published in the *Official Gazette* on May 29, 2012

CAREFUSION 2200, INC.,

Opposer,

v.

Combined Opposition Proceeding No. 91-206,212

ENTROTECH LIFE SCIENCES, INC.,

Applicant.

United States Patent and Trademark Office Trademark Trial and Appeal Board P.O. Box 1451 Alexandria, Virginia 22313-1451

APPLICANT'S NOTICE OF RELIANCE

Pursuant to Rule 704.08(b) of the Trademark Trial and Appeal Board's Manual of Procedure and 37 C.F.R. § 2.122(e), Applicant Entrotech Life Sciences, Inc. ("Applicant" or "Entrotech") hereby notifies Opposer CareFusion 2200, Inc. ("Opposer" or "CareFusion") of its reliance upon the following publicly available Internet materials (identified as Exhibits J1 – J4):

Exh. No.	Document	Title/Description	URL
J1	DOJ Article – January 9, 2014	CareFusion to Pay the Government \$40.1 Million to Resolve Allegations That Include More Than \$11 Million in Kickbacks to One Doctor	http://www.justice.gov/opa/p r/carefusion-pay- government-401-million- resolve-allegations-include- more-11-million-kickbacks
J2	Modern Healthcare Article April 26, 2013	CareFusion Plans to Pay \$41M settlement re marketing and selling of ChloraPrep products	http://www.modernhealthcar e.com/article/20130426/NE WS/304269968
J3	Law 360 Article – April 26, 2013	CareFusion to Pay \$41M To End Marketing Probe	http://www.law360.com/articles/436596/carefusion-to-pay-41m-to-end-marketing-probe)
J4	Allnurses – Networking site for Nurses	ChloraPrep Allergies? January 28, 2007	http://allnurses.com/operatin g-room-nursing/chloraprep- allergies-203871.html

Applicant will rely upon these publicly available Internet materials to establish:

(1) that confusion between Applicant's CHLORADERM, CHLORABSORB,

CHLORABOND, and CHLORADRAPE marks at issue in this Opposition, on the one hand, and Opposer's CHLORAPREP and CHLORASHIELD marks at issue in this Opposition, on the other hand, is not likely; (2) the weakness of the CHLORAPREP mark and product and any goodwill Opposer alleges either may have; (3) the dissimilarity of the channels of trade and marketing/advertising at issue in this Opposition; and (4) Opposer's reputation in the industry.

Dated: May 21, 2015 Respectfully submitted,

FISH & RICHARDSON P.C.

By:

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Attorneys for Applicant,

ENTROTECH LIFE SCIENCES, INC.

EXHIBIT J1

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Thursday, January 9, 2014

CareFusion to Pay the Government \$40.1 Million to Resolve Allegations That Include More Than \$11 Million in Kickbacks to One Doctor

CareFusion Corp. has agreed to pay the government \$40.1 million to settle allegations that it violated the False Claims Act by paying kickbacks and promoting its products for uses that were not approved by the Food and Drug Administration, the Justice Department announced today. CareFusion, a California-based medical technology company, develops, manufactures and sells pharmaceutical products, including products sold under the trade name ChloraPrep.

"When companies pay kickbacks to doctors, especially doctors involved in setting standards for the health care industry, they undermine the integrity of the health care system," said Assistant Attorney General for the Justice Department's Civil Division Stuart F. Delery. "Corrupting the standard-setting process through kickbacks can affect the health care treatment choices that doctors and hospitals may make for patients."

The settlement resolves allegations that, under agreements entered into in 2008 by CareFusion's predecessor, CareFusion paid \$11.6 million in kickbacks to Dr. Charles Denham while Denham served as the co-chair of the Safe Practices Committee at the National Quality Forum, a non-profit organization that reviews, endorses and recommends standardized health care performance measures and practices. The government contends that the purpose of those payments was to induce Denham to recommend, promote and arrange for the purchase of ChloraPrep by health care providers. ChloraPrep has been approved by the Food and Drug Administration for the preparation of a patient's skin prior to surgery or injection.

This settlement also resolves allegations that, during the period between September 2009 and August 2011, CareFusion knowingly promoted the sale of ChloraPrep for uses that were not approved by the Food and Drug Administration, some of which were not medically accepted indications, and made unsubstantiated representations about the appropriate uses of ChloraPrep.

"Health care fraud drives up the cost of health care and jeopardizes the strength of our health care system," said U.S. Attorney for the District of Kansas Barry Grissom. "This case demonstrates that our fight against health care fraud is helping to protect all Americans, including the elderly, the disabled and the most vulnerable among us."

The settlement resolves a lawsuit filed by Dr. Cynthia Kirk, a former vice president of regulatory affairs for the Infection Prevention Business Unit of CareFusion, under the qui tam, or whistleblower, provisions of the False Claims Act, which allow private citizens with knowledge of false claims to file suit on behalf of the government and to share in any recovery. The whistleblower's, or relator's, share in this case is \$3.26 million.

This settlement illustrates the government's emphasis on combating health care fraud and marks another achievement for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by Attorney General Eric Holder and Health and Human Services Secretary Kathleen Sebelius. The partnership between the two departments has focused efforts to reduce and prevent Medicare

5/19/2015 CareFusion to Pay the Government \$40.1 Million to Resolve Allegations That Include More Than \$11 Million in Kickbacks to One Doctor | OPA | Depart...

and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in this effort is the False Claims Act. Since January 2009, the Justice Department has recovered a total of more than \$17 billion through False Claims Act cases, with more than \$12.2 billion of that amount recovered in cases involving fraud against federal health care programs.

The settlement with CareFusion was the result of a coordinated effort among the Commercial Litigation Branch of the Justice Department's Civil Division, the U.S. Attorney's Office for the District of Kansas, the U.S. Department of Health and Human Services Office of Inspector General and the Food and Drug Administration Office of the Chief Counsel.

The lawsuit is captioned *United States ex rel. Kirk v. CareFusion et al.*, No. 10-2492 (D. Kan.) The claims resolved by the settlement are allegations only; there has been no determination of liability.

14-021 <u>Civil Division</u>

Updated September 15, 2014

EXHIBIT J2

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CareFusion plans to pay \$41M settlement

By Joe Carlson | April 26, 2013

CareFusion Corp., the publicly traded devicemaker spun off from Cardinal Health, announced that it will enter into an agreement with federal investigators to pay \$41 million and avoid criminal prosecution for its past sales and marketing of antiseptic surgical wipes.

A company announcement did not describe the exact allegations, but the San





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Diego-based firm has received three rounds of subpoenas since April 2011 looking for documents on how the company markets and sells ChloraPrep sterile skin preparation products to physicians, company filings with the Securities and Exchange Commission say.

"This is a significant settlement," said Drinker Biddle & Reath partner Jesse Witten. "Any time there is a nonprosecution agreement, that is significant. That means the government thinks they could have charged the case criminally. We'll learn a lot more when the settlement is finalized and the criminal information is filed."





The agreement in principle announced Thursday would resolve the allegations and have the company enter what it called a "nonprosecution agreement" that would last an undisclosed period of time.

A spokesman with the Kansas U.S. attorney's office, which issued administrative subpoenas to CareFusion for the investigation, could not comment on the agreement or the case against the company.

Because "many months" may separate agreements in principle and final settlements, it's not unusual for publicly traded companies to announce early agreements long before they're finalized, Witten said.

"Enforcement against drug and device and supply companies is very active right now, and cases that would not have been pursued in a criminal manner in the past are more and more being pursued by the criminal

prosecutors," he said.
"Healthcare fraud is such
a priority in the
Department of Justice that
they are devoting criminal
resources to it."

CareFusion was spun off from Cardinal Health in 2009. The company's infection-prevention business, which includes the ChloraPrep products, took in \$576 million in revenue in 2012, up 1.4% from the prior year.

CareFusion's biggest businesses are in medication-dispensing and infusion pumps, making up slightly more than half of its \$3.6 billion in revenue in the fiscal year ended June 30, 2012. The company earned \$293 million in income that year, posting a net margin of 8%, its SEC filing says.

Shares of CareFusion on the New York Stock Exchange had declined about 2.4% by 3 p.m. ET on Friday, to \$33.64. Friday's agreement is expected to reduce the company's earnings by 15 cents per share in the third quarter as it records a charge to establish a reserve account for the settlement.

The company currently manufactures and sells its infusion pumps under a consent decree with the Food and Drug Administration that dates back to 2007. In 2010, after enhanced corporate compliance and repairs to equipment that was recalled or seized by the FDA, CareFusion resumed manufacturing and selling infusion pumps.

Follow Joe Carlson on Twitter: @MHJCarlson

Tags: Compliance, Fraud, Income, Physicians, Revenue, Suppliers, Supply Chain

Comments

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EXHIBIT J3

CareFusion To Pay \$41M To End Marketing Probe

Marketing Probe	
By Gavin Broady	Share us on:

Law360, New York (April 26, 2013, 7:22 PM ET) -- CareFusion Corp. on Thursday announced that it will pay \$41 million under an agreement in principle with the U.S government to avoid prosecution and resolve investigations related to the sales and marketing practices of its antiseptic medical wipes.

CareFusion, a former Cardinal Health Inc. unit, said the allegations concerned its marketing of ChloraPrep preoperative skin products as well as its relationship with health care professionals. As part of the agreement, CareFusion has entered into a nonprosecution agreement and agreed to cooperate with the government.

"We are pleased to have reached this important milestone as we continue to build our foundation for future growth," CareFusion chairman and CEO Kieran T. Gallahue said in a statement Thursday. "Since our spinoff, we have made significant investments to improve our quality systems, including our sales and marketing practices, and we remain committed to adhering to the highest standards."

CareFusion did not provide further details of the governments investigations, but in U.S. Securities and Exchange Commission filings the company has copped to receiving at least three federal administrative subpoenas over the past two years.

The first subpoena was brought by the U.S. Department of Justice through the U.S. attorney for the District of Kansas in April 2011. The following September, the Office of Inspector General of the Department of Health and Human Services issued a second subpoena. The DOJ hit CareFusion with a third subpoena in August.

Neither office was immediately available for comment Friday.

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Pepper Hamilton Faces ADA Suit From Atty With Sleep Illness In the SEC filings, CareFusion said all three subpoenas sought documents and other materials concerning its ChloraPrep marketing and sales as well as its relationship with health care professionals and noted that it was cooperating with the DOJ and OIG.

On Thursday, CareFusion said it expected to establish a reserve for the expected \$41 million settlement in the third quarter of 2013 and noted that the deal remained subject to the completion and execution of the final settlement agreement.

San Diego-based CareFusion spun off from Cardinal Health's clinical and medical products business to become a public company in September 2009. In addition to automated medication and patient identification systems, CareFusion makes infusion pumps, ventilators, skin prep products, surgical instruments, diagnostic products and services for data-mining surveillance. It has about 14,000 employees.

CareFusion recently launched a malpractice suit against Foley & Lardner LLP in California, accusing the firm in a March **complaint** of botching of several patent disputes and overbilling the company.

The company claims Foley & Lardner and its attorneys did not use professional levels of "skill, prudence and diligence" when serving as the company's counsel in a patent fight with B. Braun Medical Inc. involving two separate suits as well as in a similar suit involving Hospira Inc., causing damages to CareFusion.

--Additional reporting by Daniel Wilson. Editing by Lindsay Naylor.

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EXHIBIT J4



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ChloraPrep Allergies?

by **Marie_LPN, RN** Jan 28, '07 | 32,752 Views | <u>20 Comments</u>

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Recently (appx. 3 months ago), one of our orthopod groups decided to switch to ChloraPrep for all of their Duraprep-prep cases, after reading an article on its effectiveness. But they're noticing that most of the pts. coming back for their post-op visit have had post-op allergic skin reactions, and so far it seems like the ChloraPrep is doing it (the Ioban, Xeroform gauze, Scarlet Red, and latex were ruled out).

Haven't heard from the company that makes ChloraPrep yet (sent the sales rep an email a few days ago), but that's still in the works. Meanwhile, i put Duraprep back on their preference sheets, and Chloraprep is only used on their cases when there's a betadine allergy.

Has anyone else had this issue with ChloraPrep in any surgical or nursing specialty?



Like?





chloraprep or nursing

post op



About Marie_LPN, RN

From 'Where my heart is'; 38 Years Old; Joined Jun '03; Posts: 17,031; Likes: 940.

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Register & Get Answers Today!



Jan 30, '07 by TracyB,RN

We're in the process of switching over to Chlora-Prep. Last week used it & thought the guy was developing a hive, showed the surgeon, who disagreed. I used to work for an allergist so I've seen lots of hives, but anyway, the patient was fine during surgery. Didn't hear of any problems afterwards.

I wonder if the problems are stemming from the Chlora-Prep staying in contact with the skin TOO long, since that stuff is beastly to remove. Our rep said that the only people who should have a problem with reactions are those who are allergic to green #6 (?) food dye & that color was chosen b/c of the extremely low rate of that.

I don't like how it leaks out of the opposite end of the sponge & recovery nurses don't like it b/c of checking cap refill on extremities.





Jan 30, '07 by Marie_LPN, RN

The company has a clear and orange version of ChloraPrep also. We're getting the same problems from the clear, green/blue, and the orange.

sauconyrunner likes this.

Like?





Jan 30, '07 by TracyB,RN

Hmmm.... Have you heard back from the rep yet? I glanced at the website briefly & couldn't find any info on reactions. Even checked the MSDS on the site to see what the inactive ingredients are. No luck there, either.

It's mostly your ortho docs using it? Any other services? We have been using the clear for quite some time for perm-cath insertions, but nothing else really & no complaints that we get to hear about.

We only have the green & clear.

Rep recommended to go over, say toes or fingers, to remove the colored solution. Supposedly, going over the color with the clear helps to remove the color from nailbeds... sounds like a money maker to me, LOL.

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I've been sick with upper respiratory issues the past 2 days, so I haven't been able to talk with anyone at work about this. Hopefully, this fever breaks & the non-stop coughing stop so I can stop using this stupid nebulizer Q4 & get back to work. I'm BORED!!!!!

Last edit by TracyB,RN on Jan 30, '07: Reason: another thought.

#3 Like?



Jan 30, '07 by *EricJRN*

We use ChloraPrep for some things in the NICU (like blood cultures) but our babies rarely have allergic responses to anything. I do notice that when you break the seal, only one side of the sponge seems to be wet.

#4

Like?



Jan 31, '07 by ewattsjt

We were in the process of switching over to chloraprep and the docs didn't like it. It seemed to irritate the skin if it all wasn't removed vs. dura prep mainly irritating tender areas. Another problem that we encountered is that in long procedures such as multi level spine cases; the ioban quits sticking to chloraprepped areas before the end of the case.

#5

Like?



Jan 31, '07 by Marie_LPN, RN

0

66 Quote from TracyB,RN

Hmmm.... Have you heard back from the rep yet?

Nope. He's never been known for prompt attention. :stone

66

I glanced at the website briefly & couldn't find any info on reactions. Even checked the MSDS on the site to see what the inactive ingredients are. No luck there, either.

I know, that's why i contacted the rep next. The website's kinda vague on this.

66

It's mostly your ortho docs using it? Any other services? We have been using the clear for quite some time for perm-cath insertions, but nothing else really & no complaints that we get to hear about.

Our vascular docs were using the green, clear, and orange for their access cases, and ironically, they have no reactions reported on any of those cases.

The gernal docs are using CloraPrep though (all colors) and are getting the same issue that my ortho docs are.

The gyn docs didn't want to switch, so they're still using DuraPrep.

One of the things i went over with the ortho docs (boy that was a fun meeting, not) was about their pre-op orders for site prep. We have two that want the operative sites washed with BetaSept the morning of surgery, so i thought maybe the 'double cleaning' was making the skin extra sensitive. But the same kind of skin reaction are happening with the pts. that aren't getting a pre-op scrub.



I've been sick with upper respiratory issues the past 2 days, so I haven't been able to talk with anyone at work about this. Hopefully, this fever breaks & the non-stop coughing stop so I can stop using this stupid nebulizer Q4 & get back to work. I'm BORED!!!!!

Ew, sounds like the same stuff everyone i work with is passing around. Take care of yourself.:smilecoffeecup:

#6 Like?



Jan 31, '07 by Marie_LPN, RN

0



We were in the process of switching over to chloraprep and the docs didn't like it. It seemed to irritate the skin if it all wasn't removed vs. dura prep mainly irritating tender areas. Another problem that we encountered is that in long procedures such as multi level spine cases; the ioban quits sticking to chloraprepped areas before the end of the case.

That's why one of our ortho docs refuses to use ChloraPrep on his total joint cases. The Ioban started peeling back less than 20 minutes into the case.

#7 Like?



May 17, '08 by akasha2211

I recently had day surgery and had an extensive reaction to the chloraprep (i.e. red raised rash everywhere the prep was used which started approx. 36 hours post-op). The rash, although resolving, is still visible nearly 2 weeks post-op. Fortunately, I have no allergy to iodine, so I'll ask for betadine should I ever again need surgery.

I'm wondering if there may be a greater incidence of reaction (or more severe reaction) in individuals with other allergies. I have severe allergies to several

antibiotics, as well as latex and am wondering if any of you are aware of a relationship between such allergies and reaction to chloraprep. Thanks. #8 Like? Aug 17, '08 by otiscokat It isn't real common, but I am allergic to the active ingredient in Chloraprep. It would be weird if all the ortho pts. were allergic. About 2/3 of our docs use it with no problems, that I have heard about. Like? Oct 4, '08 by retired1988 I found out I was sensitive to this prep and it made for great discomfort after insertion of mammosite catheter into my breast. The insertion site and the internal breast felt on fire and itched the evening after insertion. I was miserable for two days with sense of pressure and discomfort inside the breast. day 3 the pressure finally lessened. Thank goodness I had remaining percocet from the lumpectomy to deal with the pain. Ended up being more painful than the stereotatic biopsy and the lumpectomy plus sentinel node biopsy. I wish they would have used betadine. If time permits, patients to undergo procedures need to have skin tested for

sensitivity in the doctor office before the procedure. Help make sure not to make an unpleasant experience even more unpleasant. I will insist on this before any other invasive procedure.

Like?

Oct 6, '08 by TraciBdarn VERY interesting thread...

We were led to believe that chloroprep wouldn't cause this type of reaction...

lots of questions.. but I'll sit on them for now

#11 Like?

Apr 20, '12 by bechuven Was prepped with Chloraprep for hand/wrist surgery on 4/16/12. By that

> evening I had a shingles-like burning/itching on the preppped area. Washed off what I could and applied Benadryl cream, to no avail. By the next evening,

additionally had itchy rash on trunk and shortness of breath. Oral Benadryl relieved the new symptoms, but not the burning itch. Went to the surgeon's office where they cleaned the area (not the incision sites) with Aloe wipes. I applied more Benadryl cream. It is now 4 days, still itching, and when I uncovered the incision today because it was more tender, found it was red, swollen, and the area covered with blisters. I'm very unhappy that the manufacturer and medical journals deny adverse effects despite overwhelming online evidence to the contrary.

#12 Like?



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CERTIFICATE OF SERVICE

I hereby certify that, on this 21st day of May, 2015, a true and correct copy of **APPLICANT'S NOTICE OF RELIANCE** has been served by electronic mail upon Opposer's attorneys of record in this proceeding at the following electronic addresses:

Joseph R. Dreitler, Esq. Mary R. True, Esq. Dreitler True, LLC jdreitler@ustrademarklawyer.com mtrue@ustrademarklawyer.com

> <u>/s/ April R. Morris</u> April R. Morris